

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Jason A. A. West *et al.*

Confirmation No.: **4414**

Serial No.: **10/701,097**

Group Art Unit: **1744**

Filing Date: **November 4, 2003**

Examiner: **Nathan Andrew Bowers**

For: **Microfluidic Integrated Nanoarrays for Biological Detection**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request review of the final rejection in the above-identified application.

No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s). No more than five (5) pages are provided.

/Jeffrey H. Rosedale/

Date: May 1, 2007

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REMARKS – REASON FOR REVIEW

Claims 1-114 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Pat. App. No. 2004/0209354 to Mathies *et al.* (“the Mathies application”) and U.S. Pat. App. No. 2004/00337739 to McNeely *et al.* (“the McNeely application”). Applicants respectfully submit that these rejections are improper because neither the September 7, 2006, nor the February 7, 2007, Office Actions sets forth all of the basic requirements of a *prima facie* case of obviousness that is required by MPEP § 706.02(j).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. MPEP § 2143; In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).¹ Applicants respectfully submit that because the February 7, 2007 Office Action (the “Office Action”) does not set forth all of these elements, the rejection should be reconsidered and withdrawn.

The Office Action alleges that it would have been obvious to replace the capillary electrophoresis system disclosed in the Mathies application with a detection system dependent on the use of microarrays and to utilize a system of microarrays to detect analytes following purification in the apparatus disclosed by the Mathies application. Applicants respectfully assert that there is no motivation to substitute a microarray for the capillary electrophoresis system of the Mathies application.

It is known in the art that capillary electrophoresis comprises placing one or more species into a conduit that spans two electrodes and then applying an electric field so as to physically separate the species on the basis of the species’ **size** and **electric charge**.

¹ Applicants recognize that the Supreme Court’s decision in KSR Int’l Co. v. Teleflex Inc., 550 U.S. ____ (April 30, 2007), questioned the Federal Circuit’s application of the “teaching-suggestion-motivation” test for obviousness under 35 U.S.C. § 103. See KSR Slip Opinion at 11 (“We begin by rejecting the rigid approach of the Court of Appeals.”) However, Applicants observe that the USPTO has not, as of the date of this submission, issued any guidance to Examiners or to applicants regarding the new criteria, if any, to be applied in an obviousness determination. At all events, Applicants submit that the instant invention is not obvious in light of the Mathies or McNeely applications, either individually or in combination, under the teaching-suggestion-motivation analysis or under any new obviousness analysis adopted by the Federal Circuit and/or the USPTO in light of the KSR decision.

Information regarding the **size** of a given species is then obtained by determining the distance a given species traveled within the conduit under the electric field.

By contrast, microarrays are “collection[s] of probes synthesized, attached, or dispersed on a substrate,” (see pending Application at [0035]) and distinguish between different species based on differences in the species’ **structures** and the species’ ability to bind to specifically-structured probes located within the microarray. The microarray is then inspected to determine which species have bound to which probes so as to obtain information regarding the **structure of the sample molecules** (*e.g.*, the sequence of nucleotides comprising a DNA sample) comprising a given sample. By contrast, capillary electrophoresis, as discussed, provides information regarding the **size of sample molecules**.

Accordingly, Applicants submit that capillary electrophoresis and microarrays (a) function by wholly different mechanisms; and (b) provide qualitatively different information regarding processed samples. Because capillary electrophoresis and microarrays function by such different mechanisms and provide such different information (sample **size** and sample **structure**, respectively), Applicants submit there is no motivation to combine the Mathies and McNeely applications and perform the substitution suggested in the Office Action. See MPEP § 2143.01; In re Mills, 916 F.2d 680, 16 USPQ 2d 1430 (Fed. Cir. 1990) (the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination). Because there is no motivation to perform the substitution, the Office Action does not establish a *prima facie* case of obviousness, and claim 1 should therefore be allowed. See MPEP § 2143; In re Vaeck, 947 F.2d 488.

Second, Applicants respectfully disagree with the Office Action’s assertion that “it would have been obvious to utilize a system of microarrays to detect analytes following purification in the apparatus disclosed by [the Mathies application].” (Office Action at 4.) Claim 1 of Applicants’ invention describes:

“**A microfluidic chip**, comprising:

a plurality of vias;

a functionalized porous polymer monolith capable of being in fluid communication with at least one of said vias;

a microarray capable of being in fluid communication with said functionalized porous polymer monolith; and

an observation port through which at least one target disposed within said microarray is capable of being detected.” (emphasis added).

Thus, Applicants’ claim 1 contemplates that the various components of the invention – including, *inter alia*, the **microarray** and the **functionalized porous polymer monolith** – of the claimed invention are **integrated** into a **microfluidic chip**. Applicants submit that the Mathies and McNeely applications, either individually or in combination, do not teach the connection of a porous polymer monolith and a microarray within an integrated device, such as a microfluidic chip. MPEP § 2143.02.

The Office Action alleges, without citation to specific paragraphs of the Mathies application, that it would have been obvious to utilize a system of microarrays to detect analytes following purification in the apparatus disclosed by the Mathies application. (Office Action at 4.) This allegation, however, is not supported by the Mathies application.

As the Office Action recognizes, however, the Mathies application does not teach the use of **microarrays** or, moreover, teach an **integrated device**, such as a microfluidic chip, that comprises a **microarray** connected to a porous polymer monolith. (See Office Action at 3 (“Mathies, however, teaches that detection is accomplished using capillary electrophoresis **instead of a microarray.**”) (emphasis added). To the extent the Office Action alleges that capillary electrophoresis systems and microarrays are interchangeable, Applicants refer the Review Panel to the previous discussion in this Pre-Appeal Brief that highlights the structural and functional differences between capillary electrophoresis and microarrays. Applicants also observe the Mathies application does not describe fabrication within an integrated device, which fabrication applicants submit is necessary to any argument that a microarray connected to a porous polymer monolith in an integrated device is taught by the Mathies application.

To the extent the Office Action relies on the McNeely application to argue that the combination of a porous polymer monolith connected with a microarray in an integrated device is taught by the cited references, Applicants respectfully submit that the McNeely application does not support this reliance. While the McNeely application states at paragraphs [0157]-[0160] that connecting pre-processing modules to the interface device would be possible, the McNeely application contains no discussion, illustration, or teaching

regarding an **integrated device** comprising a microarray connected to a pre-processing module also located within the integrated device. Accordingly, because neither the Mathies application nor the McNeely application – either individually or in combination – teach Applicant’s claimed microfluidic chip comprising, *inter alia*, a microarray capable of being in fluid communication with a porous polymer monolith, the Office Action fails to establish a *prima facie* case of obviousness, and claim 1 should be allowed. See MPEP § 2143; In re Vaeck, 947 F.2d 488.

Accordingly, Applicants submit that the rejection of claim 1 is improper and should be withdrawn, and that claim 1 and all dependent claims related to claim 1 should be allowed. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) (any claim depending from an independent claim nonobvious under 35 U.S.C. § 103 is itself nonobvious.)

* * * * *

Applicants submit that the foregoing complies with the submission requirements of the Pre-Appeal Brief Request for Review. Applicants also submit that all pending claims are in condition for allowance and earnestly solicit the Review Panel to allow the application on the existing claims. Should any member of the Review Panel desire any additional information, they are requested to call the undersigned attorney at 215-568-3100.

Respectfully submitted,

Date: May 1, 2007

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